

Message

From: Ona Maune [ona.maune@bayer.com]
Sent: 6/12/2020 2:49:38 PM
To: Schmid, Emily [Schmid.Emily@epa.gov]
CC: James Nyangulu [james.nyangulu@bayer.com]; Ian Murphy [ian.murphy@bayer.com]; Gerber, Theresa [Gerber.Theresa@epa.gov]
Subject: RE: EPA# 71995-29 Roundup Weed & Grass Killer Concentrate Plus ML Amendment: Submitted 8/22/2019 (CDX_2019_006852)

Thanks Emily,

I understand you're very busy trying to meet PRIA timelines. We would appreciate if you could possibly fit both of these master label reviews on your full plate. Any feedback would be appreciated.

Kindest Regards, Ona

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Monday, June 8, 2020 9:48 AM
To: Ona Maune <ona.maune@bayer.com>
Cc: James Nyangulu <james.nyangulu@bayer.com>; Ian Murphy <ian.murphy@bayer.com>; Gerber, Theresa <Gerber.Theresa@epa.gov>
Subject: RE: EPA# 71995-29 Roundup Weed & Grass Killer Concentrate Plus ML Amendment: Submitted 8/22/2019 (CDX_2019_006852)

Hi Ona,

Theresa sent over both labels reviews to me last week but as you can imagine, I have a lot of high priority things competing for my attention at the moment. I know you are in a hurry for these so I will try to get to them as soon as I can but need to prioritize some other things before I can get to non-PRIA actions.

Best regards,
Emily

From: Ona Maune <ona.maune@bayer.com>
Sent: Friday, June 05, 2020 10:29 AM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: James Nyangulu <james.nyangulu@bayer.com>; Ian Murphy <ian.murphy@bayer.com>
Subject: RE: EPA# 71995-29 Roundup Weed & Grass Killer Concentrate Plus ML Amendment: Submitted 8/22/2019 (CDX_2019_006852)

Good Morning Emily,

We're following up on the status of both of these high priority master label amendment reviews. We would appreciate any feedback, as we're at a critical step of finalizing product labels for the 2021 season; as we'll still need to complete State label amendments prior to production. I do not have Theresa's direct email address to communicate directly. Thanks in advance.

Kindest Regards, Ona

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Friday, May 29, 2020 2:26 PM
To: Ona Maune <ona.maune@bayer.com>
Cc: James Nyangulu <james.nyangulu@bayer.com>; Ian Murphy <ian.murphy@bayer.com>

Subject: RE: EPA# 71995-29 Roundup Weed & Grass Killer Concentrate Plus ML Amendment: Submitted 8/22/2019 (CDX_2019_006852)

Hi Ona,

I haven't seen these for secondary yet. I think Theresa has been busy with some PRIAs this week but I'm sure she'll get to them as soon as she can.

Best regards,
Emily

From: Ona Maune <ona.maune@bayer.com>

Sent: Friday, May 29, 2020 9:50 AM

To: Schmid, Emily <Schmid.Emily@epa.gov>

Cc: James Nyangulu <james.nyangulu@bayer.com>; Ian Murphy <ian.murphy@bayer.com>

Subject: RE: EPA# 71995-29 Roundup Weed & Grass Killer Concentrate Plus ML Amendment: Submitted 8/22/2019 (CDX_2019_006852)

Good Morning Emily,

We're following up on the status of these master label amendments, which Theresa thought she could start reviewing last week. You mentioned they would also need your secondary review. As you know we're anxious to get both labels finalized soon. We're available if you or Theresa have any questions.

Thanks in Advance, Ona

From: Ona Maune

Sent: Monday, May 18, 2020 12:18 PM

To: Schmid, Emily <Schmid.Emily@epa.gov>

Cc: James Nyangulu <james.nyangulu@bayer.com>; Ian Murphy <ian.murphy@bayer.com>

Subject: RE: EPA# 71995-29 Roundup Weed & Grass Killer Concentrate Plus ML Amendment: Submitted 8/22/2019 (CDX_2019_006852)

Thanks Emily,

We really appreciate your feedback and having these reviews combined. As mentioned previously, both of these revised master labels (71995-25 & 71995-29) are residential concentrate products, which include much of the same proposed language & formatting revisions consistent with the acceptance of EPA# 71995-37 dated 3/28/2019. I've included a copy of the EPA# 71995-37 master label; and both cover letters outlining the key revisions for reference. Appreciate if you could share this information with Theresa, as it may be useful for her review.

Thanks in advance on the priority on these pending actions, as we are anxious to complete and implement both of these label revisions in the market.

Kindest Regards, Ona

From: Schmid, Emily <Schmid.Emily@epa.gov>

Sent: Monday, May 18, 2020 9:03 AM

To: Ona Maune <ona.maune@bayer.com>

Cc: James Nyangulu <james.nyangulu@bayer.com>; Ian Murphy <ian.murphy@bayer.com>

Subject: RE: EPA# 71995-29 Roundup Weed & Grass Killer Concentrate Plus ML Amendment: Submitted 8/22/2019 (CDX_2019_006852)

Hi Ona,

This one is assigned to Theresa. I checked in with her on it and she thinks she will be getting to it this week so your timing on sending this is very good.

Theresa is one of our newest reviewers but has been doing great with these label reviews so I asked her if she could take on 71995-25 too. I know you are anxious for it and Julia is really overloaded with PRIA actions so it makes sense to reassign it to her. They will still need my secondary review before Theresa can send them on but I'll try to work on them quickly after she sends them to me.

Thank you,
Emily

From: Ona Maune <ona.maune@bayer.com>
Sent: Friday, May 15, 2020 6:22 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: James Nyangulu <james.nyangulu@bayer.com>; Ian Murphy <ian.murphy@bayer.com>
Subject: EPA# 71995-29 Roundup Weed & Grass Killer Concentrate Plus ML Amendment: Submitted 8/22/2019 (CDX_2019_006852)

Good Afternoon Emily,
I hope all is well with you and your family. I'm reaching out to check on the status of this pending ML amendment for **EPA# 71995-29** submitted 8/22/2019 (CDX_2019_006852). In order to incorporate the required label claim clarifying how glyphosate works per the Glyphosate Interim Registration Review Decision posted 1/30/2020, we've revised the master label to replace current label claims with the following statement "Glyphosate works by targeting an enzyme that is essential for plant growth" (pg. 3 & 13). In addition, we've incorporated several minor changes and typo corrections consistent with recent labels. Both a clean copy (071995-00029-20200515.pdf) and a marked copy are attached.

We had not touched base previously on whether this action had been assigned to a reviewer, however I highlighted in a previous email dated 12/12/2019, the pending EPA# 71995-25 ML amendment (CDX_2018_006941) was significantly similar (more than 90% overlap) to this EPA# 71995-29 ML amendment. These could potentially be reviewed concurrently to maximize efficiencies; as we're aware your team is still significantly backlogged. Both of these actions take priority over all other pending non-PRIA actions under Company Number 71995; as we're trying to implement these label changes in the retail market.

As mentioned in recent communications I'm transitioning to a new role within Bayer, and I've copied **Ian Murphy** who has taken on the role as Federal Regulatory Affairs Manager for our consumer lawn & garden portfolio under Company No. 71995. Please include Ian on any future communications.

Kindest Regards, Ona

Ona Maune
Federal Regulatory Affairs Manager

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